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Miltenyi Biotec Receives FDA Approval for CliniMACS® CD34 Reagent System for Prevention of Graft-Versus-Host Disease in the Treatment of Acute Myeloid Leukemia

CliniMACS® CD34 Reagent System approved as a Humanitarian Use Device authorized by U.S. Federal law

CAMBRIDGE, MA and BERGISCH GLADBACH, GERMANY, January 24, 2014 – Miltenyi Biotec announced today that the U.S. Food and Drug Administration (FDA) has approved the company's CliniMACS CD34 Reagent System as a Humanitarian Use Device for the prevention of graft-versus-host disease (GVHD) in patients with acute myeloid leukemia (AML) in first complete remission undergoing allogeneic stem cell transplantation (SCT) from a matched related donor.

The CliniMACS CD34 Reagent System decreases the risk of developing GVHD, a life-threatening complication that can occur following an allogeneic transplant, in which T cells from the donor attack various tissues of the recipient. The FDA-approved device efficiently removes donor T cells from the graft prior to transplantation by enriching $CD34^+$ blood stem cells, which go on to repopulate the patient's immune and blood building systems.

"When chronic GVHD develops after stem cell transplantation, the result is a substantial decrease in the patient's quality of life," said Stefan Miltenyi, president and founder of Miltenyi Biotec. "We are very excited to be able to provide a new treatment option to clinicians and their patients having to undergo a transplantation procedure."

The FDA approval was based on data from a Phase II, single-arm, multi-center study (BMT CTN 0303) conducted by the Blood and Marrow Transplant Clinical Trials Network which is supported by The National Heart, Lung, and Blood Institute and The National Cancer Institute of The National Institutes of Health. The trial showed that following intensive myeloablative conditioning, stem cell transplantation from an identical sibling donor processed using the CliniMACS CD34 Reagent System as the sole means of GVHD prophylaxis leads to a low incidence of chronic GVHD (19 percent at two years after transplantation) without negatively affecting relapse, engraftment, overall survival or disease-free survival (Pasquini *et al.* (2012), JCO and Devine *et al.* (2011), Biol Blood Marrow Transplant).

"The low incidence of acute and chronic GVHD, in the absence of additional immunosuppression are distinct advantages in using the CliniMACS CD34 Reagent System," said Dr. Robert J. Soiffer, Chief of the Division Hematologic Malignancies at the Dana-Farber Cancer Institute and investigator in the Blood and Marrow Transplant Clinical Trials Network.

For more information regarding the availability of the CliniMACS CD34 Reagent System and Miltenyi Biotec, visit www.miltenyibiotec.com.

About Graft-Versus-Host Disease (GVHD)
Prevention of GVHD is a major unmet medical need in allogeneic stem cell transplantation. It can occur following transplantation, as the donor stem cells grow and repopulate the body's immune system. Immune cells in the transplant, called T cells, may identify the patient's body as foreign and attack tissues and organs. This attack by donor T cells on the patient's tissues is called GVHD. GVHD may cause serious damage to the liver, skin, mucosa, and gastrointestinal tract. GVHD varies from mild to severe and can result in death.

About the CliniMACS CD34 Reagent System
The CliniMACS CD34 Reagent System is an *in vitro* medical device system that uses antibodies conjugated to magnetic beads to select and enrich for $CD34^+$ blood stem cells from a donor graft prior to transplantation, while removing other cells that can cause GVHD.

About Miltenyi Biotec
With more than 1,300 employees in 22 countries, Miltenyi Biotec is a global therapy developer and provider of products and services that advance biomedical research and cell therapy. For the last 25 years, the company's innovative tools have supported research at every level, from basic and translational research to clinical application. This complete portfolio of products and solutions enables scientists and clinicians to access, analyze, and utilize primary cells and primary-derived cells. Areas of clinical focus include hematology, graft engineering, immunotherapies, and apheresis.

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